MAR 1 6 2001

Summary of 510(k) Submission K010218

Name and address of submitter

VISTAKON®, Division of Johnson & Johnson Vision Care, Inc.
7500 Centurion Parkway, Suite 100
Jacksonville, Florida 32256
Contact: Michael J. Tersak
Phone: (904) 443-1402
Date Prepared: January 23, 2001

Identification of Devices

- Trade name: VISTAKON (hefilcon C) Contact Lens Clear or Visibility Tinted With or Without UV Blocker.
- Common or usual name: Soft (hydrophilic) Contact Lens (daily wear)
- FDA Classification: Class II

Intended Use

Spherical lens The VISTAKON (hefilcon C) Soft (hydrophilic) Contact Lens (spherical) is indicated for daily wear for the correction of refractive ametropia (myopia and hyperopia) in aphakic or non-aphakic persons with non-diseased eyes who may have 1.50D or less of astigmatism.

Toric Lens The VISTAKON (hefilcon C) Soft (hydrophilic) Contact Lens (toric) is indicated for daily wear for the correction of refractive ametropia (myopia and hyperopia) in aphakic or non-aphakic persons with non-diseased eyes who may have 0.50D to 7.00D of astigmatism.

Eye care practitioners may prescribe the lens for single-use disposable wear or for frequent/planned replacement wear, with cleaning, disinfection and scheduled replacement. When prescribed for frequent/planned replacement, the lens may be disinfected using a chemical disinfection system only.

Information Provided By Reference

The following information is provided by reference to IGEL Vision Care 510(k)s; K974837 and K984523.

- Predicate Device
- Description of Device
- Non Clinical Studies
- Chemistry
- Toxicology
- Microbiology
- Clinical Studies

Continued on next page

Summary of 510(k) Submission, Continued

Conclusions drawn from studies	Validity of Scientific Data	Toxicology studies were conducted by a contract laboratory under Good Laboratory Practice Regulations. Microbiology, chemistry, shelf-life stability, and leachable studies were conducted by in-house laboratories and followed scientific protocols. The data were determined to be scientifically valid under 21 CFR 860.7. (Reference K974837 and K984523)
	Substantial Equivalence	The data presented in this Premarket Notification support that the subject devices are as safe and effective and performs as well as the predicate device when used in accordance with the labeled directions for use and for the requested indication.
	Risk and Benefits	The risks of the subject devices are the same as those normally attributed to the wearing of soft (hydrophilic) contact lenses on a daily wear basis. The benefits to the patient are the same as those for other soft (hydrophilic) contact lenses.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 1 6 2001

Vistakon
Johnson & Johnson Vision Care, Inc.
C/O Michael J. Tersak, Regulatory Specialist
P.O. Box 10157
Jacksonville, FL 32247-0157

Re: K010218
Trade Name: VISTAKON (hefilcon C) Soft (hydrophilic) Contact Lens, Clear or Visibility Tinted, with or without UV Blocker, for Daily Wear
Regulatory Class: II
Product Code: LPL
Regulation: 886.5925
Dated: January 23, 2001
Received: January 24, 2001

Dear Mr. Tersak:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-6413. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

A. Ralph Rosenthal

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Indications Statement

510(k) Number (if known): K010218

Device Name: VISTAKON (hefilcon C) Soft (hydrophilic) Contact Lens Clear or Visibility Tinted With or Without UV Blocker For Daily Wear

Indication for Use:

Spherical lens The VISTAKON (hefilcon C) Soft (hydrophilic) Contact Lens (spherical) is indicated for daily wear for the correction of refractive ametropia (myopia and hyperopia) in aphakic or non-aphakic persons with non-diseased eyes who may have 1.50D or less of astigmatism.

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PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED
Concurrence of CDRH, Office of Device Evaluation (ODE)

PRESCRIPTION USE

Jan 24 10 02 AM '01

FDA/CDRH/ODE/DHC

Prescription Use X OR Over the Counter _____

(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K010218